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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/125,114 08/18/98 PRICE

I P8129-8004

EXAMINER

HM12/0814

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ART UNIT

PAPER NUMBER

1619

DATE MAILED:

08/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/125,114

Applicant(s)

PRICE, IAN ASHLEY

Examiner

Alysia Berman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 11-15, 20-25 and 32-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 16-19, 26-31 and 38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

1. Receipt is acknowledged of the preliminary amendment filed March 27, 2001.  
Claim 38 has been added. Claims 1-38 are pending.

#### ***Continued Prosecution Application***

2. The request filed on March 27, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/125114 is acceptable and a CPA has been established. An action on the CPA follows.

#### ***Election/Restrictions***

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-10, 16-19, 26-31 and 38, drawn to a dosage form and a method of administering the dosage form, classified in class 424, subclass 465.
  - II. Claims 11-15, 20-25 and 32-37, drawn to a method of making a dosage form, classified in class 424, subclass 465.

The inventions are distinct, each from the other because of the following reasons:

4. Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process

(MPEP § 806.05(f)). In the instant case the dosage form can be made by the process of wet granulation.

5. Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Group I, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Robert Carpenter on August 10, 2001 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-10, 16-19, 26-31 and 38. Affirmation of this election must be made by applicant in replying to this Office action. Claims 11-15, 20-25 and 32-37 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

#### ***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-10, 16-19, 26-31 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. The claims are vague and indefinite because it is unclear what Applicant intends to claim is in homogeneous admixture with what. For example, is the carbonate or bicarbonate in admixture with only the ibuprofen medicament or does the admixture also contain the filler and disintegrant? Clarification is requested.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1, 4-10, 27-29 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,380,535 (535)

US '535 is directed to chewable compositions for oral delivery of unpalatable drugs (abstract). Chewable products in the form of compressed tablets or uncompressed powder are disclosed at column 2, lines 37-39. The composition comprises an unpalatable drug, a lipid and various other conventional excipients and additives. For mannitol and lactose, see column 6, lines 2-6. For microcrystalline cellulose, see column 7, lines 26-28. For sodium bicarbonate, see column 6, lines 16-28. For sodium starch glycolate, croscarmellose sodium and cross-linked polyvinylpyrrolidone (crospovidone), see column 6, lines 42-68. A compressed tablet also comprising lubricants and flow aids is disclosed at column 7, lines 20-30. An ibuprofen composition comprising 0.5-40 wt.% ibuprofen, 25-75 wt.% granulating agent (mannitol and lactose), 1-30 wt.% dispersal agent (sodium starch glycolate and croscarmellose sodium) and 0.5-7 wt.% lubricant is disclosed at column 8, lines 1-36. See also Examples 3 and 5 and claims 3 and 17 for ibuprofen, sodium bicarbonate, compressed tablets and mannitol.

The limitations of claims 4, 27 and 30 reciting up to a certain amount of components does not add anything to the claims. The phrase "up to" includes zero as a lower limit. *In re Mochel*, 470 F2d. 638, 176 USPQ 194 (CCPA 1974). Additionally, claim 28 includes zero as a lower limit. Therefore, the claims as written do not require a disintegrant, diluent or lubricant. US '535 discloses a compressed tablet comprising ibuprofen, sodium bicarbonate, a compressible filler, a disintegrant, lubricants and flow aids as instantly claimed.

***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 1-10, 16-19, 26-31 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,380,535 (535) in combination with US 4,844,907 (907).

US '535 discloses all the limitations of the claims as stated in the 35 U.S.C. 102(b) rejection above. It does not disclose a salt of ibuprofen or a solid formulation having a layer as in instant claim 26. US '907 discloses a bilayered tablet comprising a layer that contains an non-steroidal anti-inflammatory (NSAID) or salt thereof such as ibuprofen (abstract). US '907 discloses sodium salts of various NSAIDs and alkali metal salts at column 2, lines 16-33. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the tablet of US '535 in a bilayered form using

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the sodium salt of ibuprofen as taught by US '907 in order to provide a dosage form for administering more than one pharmaceutically active substance.

14. Claims 1-10, 27-31 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,380,535 (535) in combination with US 5,262,179 (179).

US '535 discloses all the limitations of the claims as stated in the 35 U.S.C. 102(b) rejection above. It does not teach ibuprofen salts. US '179 teaches that ibuprofen salt have an unpleasant taste and, therefore, it is advantageous to provide a dosage form that masks the taste of ibuprofen by incorporating an alkali metal bicarbonate into the dosage form (abstract). For the sodium salt of ibuprofen, see column 3, lines 26-30. It would have been obvious to substitute the sodium salt of ibuprofen as taught by US '179 into the dosage form of US '535 with the expectation of masking the taste of the sodium salt of ibuprofen.


### ***Correspondence***

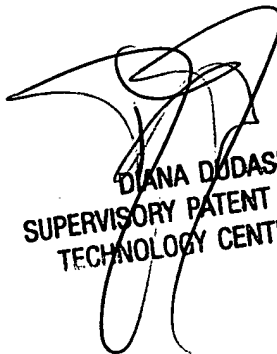
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alysia Berman whose telephone number is 703-308-4638. The examiner can normally be reached on Monday through Friday from 8:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703-308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 or 703-305-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234 or 703-308-1235.

  
Alysia Berman  
Patent Examiner  
August 10, 2001

  
DIANA DUDASH  
SUPERVISORY PATENT EXAMINER  
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